proteus DIGITAL HEALTH

MAY 07 2013

510(k) Summary

Submitted by: Proteus Digital Health Inc.
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Contact Name: Jafar Shenasa, jshenasa@proteusdh.com

Date Submitted: April 10, 2013

Name of Device

Trade name: Proteus® Patch Including Ingestible Sensor
Common name: Ingestible Event Marker
Classification name: Ingestible Event Marker (21 CFR 880.6305, Product Code OZW)

Unmodified Devices

- Proteus Personal Monitor (K113070)
- Raisin™ Personal Monitor (K093976)

General Device Description

Like the Proteus Personal Monitor (K113070), the Proteus Patch is a body-worn sensor that collects physiological and behavioral metrics including heart rate, activity, body angle, and time-stamped user-logged events generated by swallowing the Proteus Ingestible Sensor. The Ingestible Sensor is embedded inside an inactive tablet (the Pill) for ease of handling and swallowing. Once the Ingestible Sensor reaches the stomach, it activates and communicates its presence and unique identifier to the Patch. The Patch stores and wirelessly sends the physiologic, event, accelerometry, and Ingestible Sensor data to a general computing device for display.

Intended Use

The Proteus Patch, also called the Patch, is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable.

Physical Characteristics

Parameter	Value
The Patch	
Shape	One-piece: ovoid
Size	101mm x 53mm x 13mm
Weight	16g
Battery type	Lithium Polymer
Moisture susceptibility	Waterproof
Memory	4 MB
Storage temperature	Room Temperature
Relative humidity	Ambient
Ingestible Sensor	
Shape	Round
Size	6.5mm x 2.0mm
Weight	80mg

Technological Characteristics

Parameter	Sensor Technology	Method
Heart rate	Biopotential low-frequency amplifier	Digitized R wave
Activity	Accelerometer	Digitized accelerometer output
Body angle	Accelerometer	Double integration of accelerometer output
Manual event logging	Patient activated button	Digital pulse
Inter-electrode impedance	Biopotential high-frequency amplifier	Digitized impedance from small auxiliary current
Ingestible Event Marker	Bio-galvanically powered ingestible circuit	Volume conduction communication

Summary of Non-Clinical Performance Data

The three-axis accelerometer provided motion and angle relative to gravity data and was validated against a known acceleration applied against each of its three axes.

The biopotential low-frequency amplifier was used to quantify heart rate by measuring R-wave frequency based upon a modified Hamilton-Tompkins algorithm, tested using guidelines set forth in the ANSI/AAMI EC 13 standard.

The Ingestion Sensor was tested for activation time and lifetime after activation.

Summary of Clinical Performance Data

No additional clinical data were required to confirm substantial equivalence to predicate devices.

Conclusion

Based on technological characteristics, risk evaluation, and design verification of the Proteus Patch Including Ingestible Sensor, Proteus Digital Health believes that the product is safe and effective, and is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 7, 2013

Protues Digital Health, Inc
Jafar Shenasa, M.Sc., RAC
Director, Regulatory Affairs
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065

Re: K131009
Trade/Device Name: Proteus Patch including Ingestible Sesnsor
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW, DXH
Dated: April 10, 2013
Received: April 11, 2013

Dear Mr. Shenasa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K131009

Indications for Use Statement

510(k) Number (if known)	K131009
Device Name	Proteus® Patch including Ingestible Sensor
Indications for Use	The Proteus® Patch, also called the Patch, is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral heart rate, activity, and body position is desirable.

Prescription Use __X__ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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